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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,488	07/18/2003	David A. Nelson	5871-00101	4549

7590 12/15/2005
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EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,488

Applicant(s)

NELSON, DAVID A.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/31/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of system claims (1-13) and method claims (28-37) in the reply filed on November 30, 2005 is acknowledged. The traversal is on the ground(s) that the different embodiments do not put a serious burden upon the Examiner. This is not found persuasive because the embodiments in Figures 6-7 differ enough from the embodiments of Figures 8-9 to make the search burdensome. However, the Examiner agrees with the Applicant in that the elected claims are broad enough to read on Figures 8-9 (Species C-D) and would not present a serious burden to search and examine the claims in light of Species C and D. Therefore, the claims will be searched and examined in light of the elected species C and D. Claims 14-27 have been cancelled as being drawn to non-elected species A and B.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 is written as being dependent upon claim 13. The Examiner will assume claim 13 is dependent upon claim 12 for the first action. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5-12, and 28-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Greengrass et al. (5,976,110). See Figures 1-5 and the respective portions of the specification. Greengrass et al. disclose a catheter system comprising an insulated needle (12) having a proximal end configured for fluid connection and a distal end configured for insertion through tissue into a vicinity of a nerve or nerve plexus, an electrically conductive wire (14) coupled for supplying an electrical current to the insulated needle, a catheter introducer (16) having a distal end and a proximal end, wherein the distal end is made integral with the proximal end (H) or hub of the insulated needle and the proximal end of the catheter is a thread assist guide to facilitate threading of the catheter, and a catheter (20) configured for insertion within and through the catheter introducer and the insulated needle, wherein the catheter is adapted to administer fluids within the vicinity of the nerve or nerve plexus. It is the position of the Examiner that integral means "formed as a unit with another part" as it is defined in Merriam-Webster's Online Dictionary, and therefore the hub and the connector can be seen as being integral or formed as a unit when they are attached to each other. The catheter threading assist guide includes a cap portion (16b) in rotational securement with the distal end of the catheter introducer, an elastic tube (the inside of the 16B) arranged about the rotational axis of the catheter threading assist guide and fixedly attached to the cap portion and the distal end of the introducer, wherein rotation of the cap portion relative to the distal end of the introducer modifies an internal diameter of the tube to seal the orifice of the against leakage when the catheter is or is not inserted in the introducer (column 5, lines 5-10, 45-46 and column 6, lines 20-27). The system

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also includes a side port (A) that is coupled, through flexible tubing (18), to a fluid source and configured for fluid connection to the proximal end of the insulated needle, the side port extending in an orthogonal direction.

Greengrass et al. also disclose a method for administering local anesthetic or other fluids to a nerve or plexus of nerves, the method comprising providing a catheter system with an insulated needle, a catheter introducer made integral with the proximal end of the needle, a cap portion in rotational alignment with the distal end of the catheter, an elastic tube, and preloading a catheter within the introducer (See column 5, lines 61-65), rotating the cap portion to seal around the catheter, inserting the distal end of the insulated needle through the tissue and detecting when the distal end of the needle is in the vicinity of the nerve by supplying an electrical current to the insulated needle via the wire, withdrawing fluid from the vicinity of the nerve plexus through a side port (A) and administering local anesthetic or other fluids through the side port via a flexible tubing (18), the method being capable of being performed by one hand.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greengrass et al. (5,976,110) in view of Roth et al. (5,405,334). Greengrass et al. disclose all of the limitations as recited in claim 1, but do not teach to attach the hub to distal end of the catheter by use of an adhesive and do not teach to mold the hub and the distal end of the introducer to form a single component of the catheter system. Roth et al. disclose a catheter apparatus with means for delivering anesthetic agent to a subcutaneous area. Roth et al. teach to use adhesive to keep parts of the catheter system together (column 13, lines 33-37) and to mold the hub (40) and the introducer (26) together to form one unitary component (Figure 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adhesive to hold the components together or to mold the components together, as disclosed by Roth et al, to make the device disclosed by Greengrass et al so that the device would be more durable and sturdy.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greengrass et al in view of Mastrorio et al. (6,363,273). Greengrass et al. disclose a catheter system that includes all of the limitations as recited in claim 12, but does not teach to make the side port at an acute angle. Mastrorio et al. disclose an introducer element with a side port (14) extending at an acute angle to the longitudinal axis of the introducer. Therefore, it would have been obvious to one of ordinary skill in the art at

the time of the invention to make the side port, as disclosed by Greengrass et al., at an acute angle, as disclosed by Mastrorio et al., to make an introducer that will better avoid kinking of the flexible catheter attached to the side port.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


US 6,298,256 to Meyer
US 5,024,655 to Freeman et al.
US 3,682,162 to Colyer
US 6,925,333 to Krebs


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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